

§ 177.1620

and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields fluoride ion not to exceed 5 parts per million calculated on the basis of the volume of food held by the food-contact article.

[48 FR 39057, Aug. 29, 1983]

§ 177.1620 Polyethylene, oxidized.

Oxidized polyethylene identified in paragraph (a) of this section may be safely used as a component of food-contact articles, in accordance with the following prescribed conditions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene conforming to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.3 of the table in §177.1520(c). Such oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry, contains a maximum of 5 percent by weight of total oxygen, and has an acid value of 9 to 19.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in §177.1330(c), except that net acidified chloroform-soluble extractives from paper and paperboard complying with §176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in §176.170(d) (5)(iii)(b) of this chapter. If the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by such regulations. (NOTE: In testing the finished food-contact article, use a separate test sample for each extracting solvent.)

(c) The provisions of this section are not applicable to oxidized polyethylene

21 CFR Ch. I (4-1-07 Edition)

used as provided in §§175.105 and 176.210 of this chapter, and §177.2800. The provisions of paragraph (b) of this section are not applicable to oxidized polyethylene used as provided in §§175.125 and 176.170(a)(5) of this chapter and §177.1200.

§ 177.1630 Polyethylene phthalate polymers.

Polyethylene phthalate polymers identified in this section may be safely used as, or components of plastics (films, articles, or fabric) intended for use in contact with food in accordance with the following prescribed conditions:

(a) Polyethylene phthalate films consist of a base sheet of ethylene terephthalate polymer, ethylene terephthalate-isophthalate copolymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in §177.1315(b)(3), to which have been added optional substances, either as constituents of the base sheet or as constituents of coatings applied to the base sheet.

(b) Polyethylene phthalate articles consist of a base polymer of ethylene terephthalate polymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in §177.1315(b)(3), to which have been added optional substances, either as constituents of the base polymer or as constituents of coatings applied to the base polymer.

(c)(1) Polyethylene phthalate spunbonded nonwoven fabric consist of continuous filaments of ethylene terephthalate polymer and ethylene terephthalate-isophthalate copolymer to which may have been added optional adjuvant substances required in their preparation and finishing.

(2) The ethylene terephthalate-isophthalate copolymer component of the fabric shall not exceed 25 percent by weight. The filaments may be blended with other fibers regulated for the specific use and the spunbonded fabric may be further bonded by application of heat and/or pressure.

(3) The fabric shall be used only in accordance with paragraph (i) of this section.

(d) The quantity of any optional substance employed in the production of

polyethylene phthalate plastics does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitations further provided. Any substance employed in the production of polyethylene phthalate plastics that is the subject of a regulation in parts 174, 175, 176, 177, 178 and 179 of this chapter conforms with any specification in such regulation.

(e) Substances employed in the production of polyethylene phthalate plastics include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in polyethylene phthalate plastics and used in accordance with such sanction or approval.

(3) Substances which by regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter may be safely used as components of resinous or polymeric food-contact surfaces subject to the provisions of such regulation.

(4) Substances identified in this paragraph (e)(4) subject to the limitations prescribed:

LIST OF SUBSTANCES AND LIMITATIONS

(i) Base sheet:

Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid.

Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid, pyromellitic dianhydride. The level of pyromellitic dianhydride shall not exceed 0.5 percent by weight of the finished copolymer which may be used under conditions of use E through H as described in table 2 of § 176.170(c) of this chapter.

Ethylene terephthalate-isophthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid and dimethyl isophthalate or isophthalic acid with ethylene glycol. The finished copolymers contain either:

(a) 77 to 83 weight percent or

(b) At least 97 weight percent of polymer units derived from ethylene terephthalate.

(ii) Base sheet and base polymer:

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in § 177.1315(b)(3).

Ethylene terephthalate polymer: Prepared by the condensation of dimethyl terephthalate and ethylene glycol.

Ethylene terephthalate polymer: Prepared by the condensation of terephthalic acid and ethylene glycol.

(iii) Coatings:

Acrylic copolymers (CAS Reg. No. 30394-86-6): Prepared by reaction of ethyl acrylate (CAS Reg. No. 140-88-5), methyl methacrylate (CAS Reg. No. 80-62-6), and methacrylamide (CAS Reg. No. 79-39-0) blended with melamine-formaldehyde resin (CAS Reg. No. 68002-20-0). For use in coatings for polyethylene phthalate films complying with paragraph (a) of this section.

Ethylene azelate-terephthalate copolymer: The copolymer, dissolved in 1,1,2-trichloroethane and/or methylene chloride, may be used as a heat-activated sealant on polyethylene terephthalate film intended for sealing polyethylene terephthalate pouches that are used as containers of either nonalcoholic beverages or alcoholic beverages containing not more than 15 percent ethyl alcohol. The copolymer has a terephthalate/azelate molecular ratio of 1.25/1.00 and a relative viscosity of not less than 1.5 as determined by a method title "General Procedure of Determining the Relative Viscosity of Resin Polymers," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection, at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/

code_of_federal_regulations/ibr_locations.html. Total residual copolymer solvent (1,1,2-trichloroethane and/or methylene chloride) shall not exceed 0.13 milligram per square inch of film, and food contact of the film shall be limited to not more than 1 square inch per 250 grams of beverage.

2-Ethylhexyl acrylate copolymerized with one or more of the following:

Acrylonitrile.
Methacrylonitrile.
Methyl acrylate.
Methyl methacrylate.
Itaconic acid.

Vinylidene chloride copolymerized with one or more of the following:

Methacrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.
Acrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.

Acrylonitrile.
Methacrylonitrile.
Vinyl chloride.
Itaconic acid.

Styrene-maleic anhydride resin, partial 2-butoxyethyl ester, ammonium salt (CAS Reg. No. 68890-80-2). For use only as a coating for polyethylene phthalate films complying with paragraph (a) of this section, at levels not to exceed 0.025 gram per square meter (0.016 milligram per square inch) of the film, in contact with food of types VIII and IX in table 1 of §176.170(c) of this chapter, under use conditions E, F, and G in table 2 of §176.170(c) of this chapter.

(iv) Emulsifiers:

Sodium dodecylbenzenesulfonate: As an adjuvant in the application of coatings to the base sheet or base polymer.

Sodium lauryl sulfate: As an adjuvant in the application of coatings to the base sheet or base polymer.

2-Sulfoethyl methacrylate, sodium salt (CAS Reg. No. 1804-87-1). For use only in copolymer coatings on polyethylene phthalate film under conditions of use E, F, and G described in table 2 of §175.300(d) of this chapter, and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.

(v) Modifier:

1,4-Benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol and α -hydro- ω -hydroxypoly(oxy-1,4-butanediyl)
CAS Reg. No. 9078-71-1) meeting the following specifications:

Melting point: 200° to 215 °C as determined by ASTM method D2117-82, "Standard Test Method for Melting Point of Semicrystalline Polymers by the Hot Stage Microscopy Method," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Density: 1.15 to 1.20 as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For in-

formation on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

The modifier is used at a level not to exceed 5 percent by weight of polyethylene terephthalate film. The average thickness of the finished film shall not exceed 0.016 millimeter (0.0006 inch).

Hexanedioic acid polymer with 1,3-benzenedimethanamine (CAS Reg. No. 25718-70-1) meeting the specifications in §177.1500(b), item 10, when tested by the methods given in §177.1500(c). The modifier is used in polyethylene terephthalate at a level not to exceed 30 percent by weight of the polyethylene terephthalate.

Chloroform-soluble extractives shall not exceed 0.08 milligram/centimeter² (0.5 milligram/inch²) of food-contact surface of the modified polyethylene terephthalate article when exposed to the following solvents at temperatures and times indicated:

- (a) Distilled water at 49 °C (120 °F) for 24 hours;
- (b) *n*-Heptane at 49 °C (120 °F) for 24 hours;
- (c) 8 percent ethyl alcohol at 49 °C (120 °F) for 24 hours.

For use in contact with all types of foods except (a) those containing more than 8 percent alcohol, or (b) those at temperatures over 49 °C (120 °F).

(f) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (f)(1) of this section are used as provided in paragraph (f)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250 °F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to *n*-heptane at 150 °F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding food, excluding alcoholic beverages, at temperatures not to exceed 250 °F.

(g) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (g)(1) of this section are used as provided in paragraph (g)(2) of this section.

(1) *Specifications.* (i) The food contact surface meets the specifications in paragraph (f)(1) of this section; and

(ii) The food contact surface when exposed to 50 percent ethyl alcohol at 120 °F for 24 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding alcoholic beverages that do not exceed 50 percent alcohol by volume.

(h) Uncoated polyethylene phthalate plastics consisting of a base sheet or base polymer prepared as prescribed from substances identified in paragraphs (e)(4)(i) and (ii) of this section and conforming with the specifications prescribed in paragraph (h)(1) of this section are used as provided in paragraph (h)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250 °F for 2 hours yields chloroform-soluble extractives not to exceed 0.02 milligram/inch² of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to *n*-heptane at 150 °F for 2 hours, yields chloroform-soluble extractives not to exceed 0.02 milligram/inch² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used to contain foods during oven baking or oven cooking at temperatures above 250 °F.

(i) Polyethylene phthalate fabric, identified in paragraph (c) of this section and conforming with the specifications prescribed in paragraph (i)(1) of this section, is used only as provided in paragraph (i)(2) of this section.

(1) *Specifications.* Chloroform-soluble extractives shall not exceed 0.2 milligram/inch² of food-contact surface when exposed to the following solvents at temperatures and times indicated:

(i) Distilled water at 212 °F for 2 hours.

(ii) *n*-Heptane at 150 °F for 2 hours.

(iii) 50 percent ethyl alcohol at 120 °F for 24 hours.

(2) *Conditions of use.* The plastics are intended for:

(i) Dry food contact.

(ii) Bulk food (excluding alcoholic beverages) repeated use applications,

including filtration, at temperatures not exceeding 212 °F.

(iii) Filtration of bulk alcoholic beverages, not exceeding 50 percent alcohol by volume, at temperatures not exceeding 120 °F.

(j) Polyethylene phthalate plastics, composed of ethylene terephthalate-isophthalate containing a minimum of 98 weight percent of polymer units derived from ethylene terephthalate, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in §177.1315(b)(3), conforming with the specifications prescribed in paragraph (j)(1) of this section, are used as provided in paragraph (j)(2) of this section.

(1) *Specifications.* (i) The food contact surface meets the specifications in paragraph (f)(1) of this section and

(ii)(a) *Containers with greater than 500 mL capacity.* The food-contact surface when exposed to 95 percent ethanol at 120 °F for 24 hours should not yield chloroform-soluble extractives in excess of 0.005 mg/in².

(b) *Containers with less than or equal to 500 mL capacity.* The food contact surface when exposed to 95 percent ethanol at 120 °F for 24 hours should not yield chloroform-soluble extractives in excess of 0.05 mg/in².

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding alcoholic foods that do not exceed 95 percent alcohol by volume.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 18611, Apr. 8, 1977; 44 FR 40886, July 13, 1979; 45 FR 6541, Jan. 29, 1980; 47 FR 11844, Mar. 19, 1982; 47 FR 53346, Nov. 26, 1982; 48 FR 30361, July 1, 1983; 49 FR 10110, Mar. 19, 1984; 50 FR 31047, July 24, 1985; 51 FR 3772, Jan. 30, 1986; 52 FR 32917, Sept. 1, 1987; 54 FR 15750, Apr. 19, 1989; 54 FR 24898, June 12, 1989; 60 FR 57927, Nov. 24, 1995; 60 FR 61654, Dec. 1, 1995; 61 FR 46718, Sept. 5, 1996]

§ 177.1632 Poly (phenyleneterephthalamide) resins.

Poly(phenyleneterephthalamide) resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated contact with food.

(a) *Identity.* For the purpose of this section, the poly(phenyleneterephthalamide) resins (CAS Reg. No. 26125-61-1) are produced by the polymerization of terephthaloyl chloride